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TITLE: The impact of surgical timing in acute traumatic spinal cord injury

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14. ABSTRACT

The optimal surgical timing following a traumatic spinal cord injury (SCI) remains controversial although some studies suggest improved neurological recovery with early surgery. Consequently, there is wide variability in clinical practice and institutional guidelines regarding optimal surgical timing after a SCI. Our study will help guide clinicians in their practice and health administrators in the distribution of resources, by determining the optimal surgical delay after a traumatic spinal cord injury. The global objective of our study is to determine the impact of surgical delay on costs, length of stay, complications, and outcomes (neurological recovery, functional status and quality of life) in patients with a traumatic SCI. For the first reporting period, we have completed recruitment of traumatic spinal cord injured patients and continued with the 6-month, 1-year and 2-year follow-ups. Data collection is nearly completed (95%) and will be finished by the beginning of 2015.

15. SUBJECT TERMS
Spinal cord injury; surgery; delay; recovery; trauma; complications; length of stay; costs

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1. INTRODUCTION

The optimal surgical timing following a traumatic spinal cord injury (SCI) remains controversial although some studies suggest improved neurological recovery with early surgery. Consequently, there is wide variability in clinical practice and institutional guidelines regarding optimal surgical timing after a SCI. Our study will help guide clinicians in their practice and health administrators in the distribution of resources, by determining the optimal surgical delay after a traumatic spinal cord injury. The global objective of our prospective research is to determine the impact of surgical delay on costs, length of stay, complications, and outcomes (neurological recovery, functional status and quality of life) in a cohort of patients with a traumatic SCI. By defining the optimal surgical timing after a SCI, this study has the potential to improve the neurological and functional outcome of patients, while decreasing the costs, length of stay and complications for the acute care after a SCI. This study might ultimately modify existing guidelines for pre-hospital, en route care, and early hospital management of SCI patients in order to comply with the optimal surgical timing, and will also determine the optimal surgical timing that will minimize the rate of complications such as pressure ulcers and pneumonia.

2. KEYWORDS

Spinal cord; trauma; complications; costs; length of stay; recovery; quality of life; timing; surgery; rehabilitation; function; fracture; acute hospitalization; ASIA grade

3. ACCOMPLISHMENTS

What were the major goals of the project?

Listed below are the major goals of this project, according to the approved statement of work.

a) Recruitment of patients

As of September 30, 2014, the recruitment of patients is completed.

b) Follow-up of patients

Follow-up of patients is currently in progress. Thirty-five patients have completed their 2-year follow-up and have thus terminated their participation to this study.

c) Data collection

Data collection is ongoing. Socio-demographic, clinical, surgical and radiological data have been collected for 132 patients (95% completed). Collection of additional data related to acute hospitalization and calculation of indices by our medical archivist is also close to be completed (95% of data collected).

d) Data analysis

Data analysis will be initiated as soon as data collection is completed.

e) Publications and conferences

Nothing to report for this period

What was accomplished under these goals?

For the first year of funding, the major goals were to complete recruitment of our sample of 136 traumatic spinal cord injured patients, pursue the 6-month, 1-year and 2-year follow-up of enrolled patients, and continue the collection of socio-demographic, clinical, surgical and radiological data. As well, we planned to start the analysis of the data collected at that point.

The statement of work approved by USAMRMC was based on the hypothesis that funding would have begun on April 1, 2013. In fact, we received HRPO approval on February 21, 2014, and thus initiated the study at that time. Therefore, all activities reported in the approved statement of work are delayed by approximately 11 months (April 1, 2013 – February 21, 2014).

a) Recruitment of patients

This project was previously funded by FRSQ (2010-2012). While funded by FRSQ, we were recruiting all SCI patients, including those diagnosed with a central cord syndrome or with a spinal injury below the L1-L2 disc. Those patients were however excluded from the project funded by USAMRMC. Thus, the number of patients officially recruited under this project and reported in the annual IRB renewal request is greater than the actual number of eligible patients that were approved to be enrolled with USAMRMC funding.

As of September 30, 2014, 219 patients have been enrolled in this project. Among those 219 patients, 67 are not eligible with respect to the new inclusion/exclusion criteria (44 were diagnosed with a central cord syndrome, 23 had a spine injury below L1-L2). Twelve other patients either withdrew their consent, or did not come to any follow-up appointment. Thus, we have 140 eligible patients enrolled under USAMRMC funding. At this point, we have terminated recruitment.

Specifically, since approval of the study by HRPO on February 21, 2014, we have recruited 19 eligible patients. As mentioned in the approved statement of work, we were expecting the recruitment rate to be approximately 3.6 patients per month. The actual recruitment rate was well below what was expected, reaching only 2.4 patients per month (19 patients enrolled over an 8-month period, i.e. between February and September 2014). Over that period, eleven eligible patients declined to participate. Moreover, 19 additional SCI patients were admitted at our institution between February 2014 and September 2014, but since either they were diagnosed with a central cord syndrome (16/19) or had a spinal injury at L2 or below (3/19), they were not approached by our team. In the approved statement of

work, which considered that funding would start in April 2013, it was specified that enrollment would be completed in June 2013, representing a 2-month period for recruitment completion. In fact, we took 8 months to complete the recruitment phase, and we finished the enrollment phase in September 2014.

b) Follow-up of patients

With respect to patients' follow-up, as of September 30, 2014, 80 patients had their 6-month follow-up completed, 78 patients came for their 1-year follow-up and 35 have done their 2-year follow-up. For these 35 patients, the participation to this study is terminated.

c) Data collection

With respect to data, we have collected the information pertaining to the socio-demographic, clinical, surgical and radiological characteristics of 132 patients. Collection of information for the last 8 patients will be completed by December 2014. The medical archivist hired by our team has started working on the collection of additional data related to acute hospitalization, such as the Injury Severity Score (ISS), comorbidities and the NIRRU index used to calculate costs. This information is made available by the medical archives department following discharge of patients. Since the patients most recently enrolled in this study are still hospitalized at our institution, this information is not available yet. According to the statement of work, this portion of data collection was supposed to be finalized by December 2013. Considering the delayed initiation of this study, this portion of data collection is not finalized, but will likely be completed by January 2015.

d) Data analysis

According to the statement of work, analysis of data related to Hypothesis 1 (early surgery decreases length of stay and costs) and Hypothesis 2 (early surgery decreases the number of complications) was supposed to be initiated in October 2013. Considering that we received HRPO approval at the end of February 2014, which introduced an 11-month delay in the initiation of our study, and that data collection is 95% completed, we plan on starting the analyses of information pertaining to these outcomes as soon as all data is collected, i.e. around January 2015.

e) Publications and conferences

Nothing to report for this period

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report for this period

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, we will continue the follow-up of patients. We will also complete data collection with our medical archivist. We will analyze the data to verify the first two hypotheses related to the impact of surgical delay on costs and length of stay, as well as complications. We plan on submitting abstracts to international conferences interested in spinal cord injuries. We will also work on papers related to hypotheses 1 and 2, which we hope will be ready to submit to peer-reviewed journals around the end of the next reporting period.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES / PROBLEMS

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

The only problem that we anticipate is the compliance of patients to come to their follow-up / appointment with their treating surgeon. We will emphasize the importance of coming to each follow-up, and will offer them to fix their appointment ourselves at the best moment for them in order to decrease the inconvenience of coming to our institution.

Changes that had a significant impact on expenditures
We hired just recently the medical archivist that will help us in collecting additional data related to the acute hospitalization of patients. She began working with our team at the beginning of October 2014. This is the only change that impacted on expenditures so far.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and / or select agents
Nothing to report

Significant changes in use or care of human subjects
Nothing to report

Significant changes in use or care of vertebrate animals
Nothing to report

Significant changes in use of biohazards and / or select agents
Nothing to report

6. PRODUCTS

Publications, conference papers, and presentations
Nothing to report

Website(s) or other Internet site(s)
Nothing to report

Technologies or techniques
Nothing to report

Inventions, patent applications, and/or licenses
Nothing to report

Other products
Nothing to report

7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Please note that at our institution, a regular workday is 7 hours and the schedule is based on 35 hours of work per week. We however calculated the number of "person month" worked based on 160 hours of effort as indicated in the USAMRMC report guidelines.

Name	Dr Jean-Marc Mac-Thiong
Project role	Principal investigator / director
Researcher identifier	N/A
Nearest person month worked	0.5
Contribution to project	Supervision of staff and data collection; revision of documents
Funding support	No funding other than USAMRMC
Name	Cynthia Thompson
Project role	Research assistant
Researcher identifier	N/A
Nearest person month worked	5
Contribution to project	Data collection, reduction and analysis; communication with USAMRMC
Funding support	No funding other than USAMRMC
Name	Geneviève Leblanc
Project role	Research assistant
Researcher identifier	N/A
Nearest person month worked	1
Contribution to project	Recruitment and enrollment of patients
Funding support	No funding other than USAMRMC
Name	Louisane Dupré
Project role	Research nurse
Researcher identifier	N/A
Nearest person month worked	2
Contribution to project	Follow-up of patients, data collection
Funding support	No funding other than USAMRMC

Has there been a change in the active other support of the PD / PI or senior / key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

Nothing to report